IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ALPHARMA INC.,	)	**Civil Action No. 8:03-cv-01406-PJM**
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
MARK B. MCCLELLAN, M.D., PH.D. Commissioner of Food and Drugs, Food and Drug Administration	)	
	)	
and	)	
	)	
FOOD and DRUG ADMINISTRATION,	)	
	)	
Defendants.	)	

OPPOSITION TO DEFENDANTS' MOTION FOR ENLARGEMENT OF TIME

Plaintiff, Alpharma Inc. ("Alpharma"), by and through its attorneys, Keller and Heckman LLP, hereby opposes the Defendants' Motion for Enlargement of Time ("FDA Motion"), pursuant to Fed. R. Civ. P. 11(b)(1), because Defendants seek to unjustifiably delay these proceedings in order to conduct unspecified and indeterminate administrative proceedings that may, or may not, resolve issues about the present approval status of animal drug products currently being marketed to the public and in competition to Alpharma.

1. On May 13, 2003, Alpharma filed this action seeking declaratory judgment that the Food and Drug Administration ("FDA") had either not approved or improperly approved an animal drug product that PennField Oil Co. ("PennField") began

marketing to the public around December 2002 in competition with Alpharma. FDA's answer or responsive pleading is due on July 14, 2003.

2. FDA seeks to avoid stating publicly whether it has approved PennField's animal drug product and, if so, under what authority, by seeking until August 13, 2003 to file a responsive pleading. According to its Motion, FDA "expect[s]" to file a Federal Register notice within that time period "that will address the issue raised by the instant action" and "*may* alter the positions of the parties." FDA Motion, ¶¶ 3, 4 (emphasis added). If FDA succeeds in its expectation—which it may not—Alpharma anticipates that FDA will then ask this Court to stay these proceedings until FDA's administrative process has been completed. FDA offers no timetable for such a proceeding and any possible appeal therefrom. In fact, FDA fails to describe whether the "Federal Register notice" will be a proposed rulemaking, as Alpharma anticipates, or some other action. As the Court is aware, publication in the Federal Register is only the first step in a process that may take anywhere from 90 days to years to be completed. Not insignificantly, the FDA is seeking to update regulations to fix problems that the FDA not only created, but also has had many years to address. In the meantime, Alpharma expects that PennField's allegedly unapproved or improperly approved product will remain in the marketplace.

3. FDA does not assert that it does not know whether it has approved PennField's claims. Certainly, the Agency knows what approvals it has issued and the reasons for any such approvals. The Agency's knowledge of the current validity and basis of any PennField approval will not change in 30 days.

4. FDA does not, and cannot, assert that it has not had adequate time to respond timely. Alpharma brought this matter to FDA's attention in early 2003.

Specifically, on January 16, 2003, counsel for Alpharma challenged FDA about the basis of PennField's claim of approval and provided FDA with an overview of Alpharma's position, as explained in more detail in the Complaint. During subsequent regular communications with FDA counsel throughout the Spring of 2003, Alpharma reiterated its position as stated in its Complaint. On May 2, 2003, approximately two weeks prior to filing its Complaint, Alpharma advised FDA counsel that it intended to sue if necessary. Certainly, FDA has had sufficient notice to determine its response as required under the Federal Rules.

5. Alpharma needs to establish the legitimacy of PennField's product *now*. If, as Alpharma alleges, PennField's product is unauthorized, then PennField's continued sale of that product is causing Alpharma irreparable harm on a daily basis. FDA's requested delay would result in another 30 days of injury. Alpharma's Complaint addresses the current approval status of PennField's product since its introduction in December 2002. FDA can state now what that status is. FDA's attempt to resolve potential problems in its existing regulations through its administrative process should not further delay the Court's review of the legitimacy of FDA's actions or inaction, nor should it result in unnecessary further damage to Alpharma.

WHEREFORE, Alpharma respectfully requests that the Court deny Defendants' Motion.

Respectfully submitted,

Date: July 11, 2003

/s/

Douglas J. Behr, Md. Federal Bar No. 013506
behr@khlaw.com
Keller and Heckman LLP
1001 G Street, N.W.

Washington, D.C. 20001
(202) 434-4100
(202) 434-4646 (fax)

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 11th day of July, 2003, one copy of the foregoing Opposition to Defendants' Motion for Enlargement of Time was electronically filed, as well as faxed and mailed, postage prepaid, to the following:

Tarra DeShields, Esquire
Assistant United States Attorney
Office of the United States Attorney
6625 United States Courthouse
101 West Lombard Street
Baltimore, MD 21202
(410) 209-4800
(410) 962-2310 (fax)

Drake Cutini, Esquire
Trial Attorney
Office of Consumer Litigation
Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 514-1586
(202) 514-8742 (fax)

Barbara J. Alkalay, Esquire
Associate Chief Counsel
Food and Drug Administration
Rockville, MD 20857
(301) 827-9106
(301) 827-0973 (fax)

/s/
Douglas J. Behr, Md. Federal Bar No. 013506